



June 23, 2008

California Department of General Services
Real Estate Services Division
Professional Services Branch, Environmental Services Section
Attn: Valerie Namba, Senior Environmental Planner
707 Third Street, Third Floor, MS 509
West Sacramento, CA 95605-9052
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RE: Comments on DEIR Adoption of Statewide Regulations Allowing the Use of PEX Tubing

Dear Ms. Namba:

Thank you for the opportunity to comment on the *DEIR Adoption of Statewide Regulations Allowing the Use of the PEX Tubing*.

The mitigation measures outlined in 4.4-1 and 4.4-2 of Table 1-1 are not necessary as compliance with NSF/ANSI 61 is mandated by the California Plumbing Code. The additional requirements for MTBE, TBA and other Proposition 65 chemicals do not provide additional health benefits. In addition, we are requesting deletion of several chemicals from Table 4.4-1.

We are perplexed at a number of compounds that are on Table 1 that are purported to be related to HDPE and PEX. The chemicals which are being requested for deletion are benzene (71-43-2), benzothiazole (95-16-9), bisphenol A (80-05-7), carbon disulfide (75-15-0), cyclo-hexanone (108-94-1), cyclopentanone (120-92-3), diazadiketo-cyclotetradecane, nonylcyclopropane, propenyl-oxymethyl oxirane, tetrahydrofuran (109-99-9) and trichloroethylene (79-01-6).

NSF currently certifies over 280 cross-linked polyethylene products produced at 50 manufacturing sites to the health-effects requirements of ANSI/NSF Standard 61 and has 20 years of experience in evaluating PEX piping. Based on NSF's experience in reviewing the formulations of these products and conducting testing on PEX piping, NSF has not seen and would not expect to see the above chemicals present in the formulation or in NSF/ANSI 61 chemical extraction test results of PEX piping. In addition, all chemicals in the Polyurethane section should be deleted as they are not relevant for PEX. Polyurethane is not an ingredient in PEX nor is it used as a liner or coating for PEX in potable water applications.

NSF/ANSI Standard 61 is a comprehensive standard utilizing the best available technology for evaluation of drinking water system components following a risk assessment approach that considers the inter-relationships between reviewing the material formulation, product exposure and testing, product end use, normalization of laboratory testing, detection level issues, effects of short-term and long-term exposures, and an EPA-style methodology for development of drinking water acceptance criteria. The following sections outline how NSF/ANSI 61 is protective of public health.



Regulatory Status of NSF/ANSI 61

A survey of the Association of State Drinking Water Administrators found that 45 states have requirements for water treatment and distribution components to comply with NSF/ANSI Standard 61. California Code of Regulations Title 22 Section 64591 requires drinking water system components to be tested and certified to NSF/ANSI Standard 61. The 2007 California Plumbing Code Section 604.1 requires all pipe, tube, and fittings carrying water used in potable water systems intended to supply drinking water to meet the requirements of NSF/ANSI 61. NSF/ANSI Standard 61 is the only American National Standard that evaluates the health effects of chemical extraction from drinking water system components.

History of NSF 61

Before 1988, the U.S. Environmental Protection Agency issued letters of approval to manufacturers for products intended to contact drinking water. Early on, EPA recognized a need for a more thorough and standardized evaluation process for these products, yet realized that their limited resources prevented expansion of this program. As part of their assessment, they examined whether the evaluation of drinking water additives for health effects should be a government or private sector program. As a result, in 1984, the EPA issued a request for proposals for independent, not-for-profit organizations to develop standards and a certification program for products used to treat or distribute drinking water.

In response to a competitive request for proposals from the EPA in 1984, a Consortium led by NSF International agreed to develop voluntary third-party consensus standards and a certification program for all direct and indirect drinking water additives. Other members of the Consortium include the American Water Works Association Research Foundation, the Association of State Drinking Water Administrators, the Conference of State Health and Environmental Managers, and the American Water Works Association. (COSHEM has since become inactive as an organization.)

In October 1988, NSF/ANSI 61 Drinking Water System Components-Health Effects was first published. NSF/ANSI 61, and subsequent product certification against it, has replaced the USEPA Additives Advisory Program for drinking water system components. USEPA terminated its advisory role in April 1990.

Organization of NSF/ANSI 61 Joint Committee

NSF/ANSI Standard 61 is overseen by the NSF Drinking Water Additives Joint Committee comprised of representation from the regulatory community, the manufacturing industry and user groups. The American National Standards Institute accredits NSF standards development procedures to ensure a balanced committee of stakeholders develops the standards in an open process. Providing technical oversight is the NSF Council of Public Health Consultants. The council is a group of over 30 representatives from academia and local, state and federal regulatory agencies that provide technical advice and oversight of the NSF Standards.

A standing task group is NSF Health Advisory Board. This group consists of toxicologists from USEPA, Health Canada, state and provincial agencies as well as toxicologists from industry and private consulting firms. This group is responsible or reviewing and approving all allowable contaminant concentrations that are published in NSF/ANSI Standard 61.



Testing Protocol

Formulation review: As NSF/ANSI 61 is concerned about any potential contaminant that may leach from products the standard requires that formulation information on all water contact material be provided in order to identify potential extractants. This includes detailed information from manufacturers and their suppliers on composition, known or suspected impurities, and manufacturing processes for all wetted components in products submitted for evaluation.

Identification of potential extractants: Two items establish test requirements. First, Table 3.1 of the standard identifies the minimum battery of testing required and is driven by the generic type of materials used in the water contact parts. Secondly, any manufacturer specific or formulation specific analytes of concern determined during the review of the information collected are added to the test battery.

Laboratory testing: Laboratory testing provides a mechanism to establish if any of the potential extractants of concern extract under standardized testing conditions. The laboratory testing has three components: sample preparation, conditioning, and exposure. Sample preparation consists of rinsing the products with tap water to remove any debris that may occur during product shipment and handling.

Tubing is conditioned by exposure to the formulated waters for 16 days with water being changed on 12 of those days. PEX tubing is tested by exposing the tubing to formulated exposure waters, and then analyzing the exposure waters for contaminants. Three separate formulated waters are used during the product exposure. A pH 5.0 and a pH 10.0 exposure water are separately used during the exposure for extraction of metallic contaminants. A pH 8.0 water is used during the exposure for organic based contaminants. The tubing samples containing water are heated to 140°F (60°C), for domestic hot water systems or 180°F (82°C) for commercial hot systems.

ANSI/NSF Standard 61 allows for some chemicals to be present at higher initial concentrations, if they exhibit sufficient decay over the first 90 days of product use. When multiple time point data are used, the concentration for the contaminant of concern shall meet the Short Term Exposure Level on the first day of laboratory analysis and the concentration shall meet the Total Allowable Concentration/Single Product Allowable Concentration by the 90th day.

Normalization: The water collected from the final 16-hour exposure period is then analyzed for contaminants. Laboratory results must be "normalized" to adjust contaminant concentrations based on the surface area, volumes, exposure times under laboratory conditions to be reflective of the surface area, volumes and exposure times encountered by products in the field. NSF/ANSI 61 provides assumptions for the use of plumbing system components based on product size, end use, and flow rates.

Acceptance Criteria: The drinking water acceptance criteria are established through Annex A of the standard. The criteria for over 600 chemicals have been established and are listed in Annexes D and E. The requirements are based on regulated levels and health advisories where they exist and based on available toxicology data where they don't. USEPA and Health Canada representatives have established harmonized acceptance criterion for the standard where differences exist between a USEPA MCL (maximum contaminant level) and a Health Canada MAC (maximum allowable concentration).



t-Butanol

A risk assessment has been performed by NSF International (attached) for t-butanol which resulted in a pass/fail criteria of 9,000 ug/L. The results of the risk assessment performed at NSF significantly differs from the drinking water level that has been set by California. Since the time when California notification level was developed the EPA has published criteria for discounting the alpha-2u-globulin mode of action when performing a human health risk assessment. The NSF risk assessment uses current EPA criteria to address this issue and is adequately protective of public health. In addition, we would like to highlight the fact that the NSF risk assessment is based on health effects only and not based on taste and odor.

In a document dated June 2, 1999 (<http://www.oehha.ca.gov/water/pals/tba.html>) the process for derivation of the 12 ug/L California drinking water level for tertiary butanol was described, and was clearly noted as an interim assessment. The critical effect selected was male rat kidney adenoma and carcinoma observed in an NTP (1994) cancer bioassay, and a carcinogenic response to t-butanol was also considered to be supported by an increased incidence of thyroid gland follicular cell adenoma in female mice. NSF considered that the weight of evidence supported an alpha-2u-globulin mode of action for the male rat kidney tumors. This mode of action is male rat specific and not relevant to human health, and the EPA has published criteria for discounting this effect that NSF considered to be met. Likewise, the EPA (1998) has published guidance on the assessment of thyroid follicular cell tumors, concluding that thyroid tumors meeting specific criteria could be assessed using nonlinear considerations, due to apparent quantitative differences in sensitivity between rodents and humans to thyroid cancer development from thyroid-pituitary disruption. Taken together with the fact that tertiary butyl alcohol is not genotoxic, it was concluded by NSF and the external review panel that using a linear approach in deriving oral risk values for this chemical was not appropriate based on the current best science.

Detection limit of t-butanol

Since the development of the DEIR, NSF has lowered the detection limit for t-butanol. As there is no EPA approved method for the analysis of t-butanol in water, NSF has developed a method utilizing a gas chromatograph instrument operated in the splitless-injection mode with a Phenomenex ZB-1 column and a flame-ionization detector (GC-FID). This method allows NSF to detect t-butanol in the raw exposure water down to 20 ug/L or 20 ppb and has a linear calibration range up to 2,000 ug/L.

MTBE

A risk assessment has been performed by NSF International (attached) for MTBE which resulted in a pass/fail criteria of 100 ug/L. Please note this should be corrected in the DEIR which reports the NSF value as 50 ug/L. The difference between NSF's acceptance criteria (100ug/L) and California's maximum contaminant level (13 ug/L) is a difference in risk management approach of using a 10⁻⁵ safety factor vs a 10⁻⁶ safety factor. Both factors are acceptable given current EPA risk management criteria and are protective of public health. NSF has chosen the 10⁻⁵ safety factor and this is appropriate given that the NSF/ANSI 61 testing is based on new materials at the beginning of their life which represents a worst case scenario. The assumption behind the California maximum contaminant level is a continuous exposure of the chemical at the regulated level. Concentrations of contaminants leaching from plumbing products decay over a period of time, and should not be assumed to be consistent and continuous over the lifetime of the product. This difference makes a direct comparison between the NSF acceptance criteria and the MCL difficult to conduct.



NSF International

Ann Arbor, MI • Brussels, Belgium

Thank you for the opportunity to provide comments. Please contact me if you need additional comments or clarification on the information provided.

Sincerely,

A handwritten signature in cursive script that reads "Lori Bestervelt, Ph.D." followed by a stylized flourish.

Lori Bestervelt, Ph.D.

Senior Vice President and Chief Technical Officer